# In the United States Court of Federal Claims

# OFFICE OF SPECIAL MASTERS No. 20-0729V

CARLINGTON KEITH MYERS,

Chief Special Master Corcoran

Petitioner,

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SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

Filed: October 29, 2024

Vasiliki D. Koutsogiannis, Law Office of James Snell, Jr. LLC, Lexington, SC, for Petitioner.

James Vincent Lopez, U.S. Department of Justice, Washington, DC, for Respondent.

# **DECISION**<sup>1</sup>

On June 17, 2020, Carlington Keith Myers filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*<sup>2</sup> (the "Vaccine Act"). Petitioner alleges that he suffered Guillain-Barré syndrome ("GBS") that was caused in fact by an influenza ("flu") vaccine received on November 23, 2016.<sup>3</sup> Petition at 1. Petitioner alternatively asserts a significant aggravation claim, which

<sup>&</sup>lt;sup>1</sup> Because this Decision contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims' website, and/or at <a href="https://www.govinfo.gov/app/collection/uscourts/national/cofc">https://www.govinfo.gov/app/collection/uscourts/national/cofc</a>, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). This means the Decision will be available to anyone with access to the internet. In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

<sup>&</sup>lt;sup>2</sup> National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2018).

<sup>&</sup>lt;sup>3</sup> Although GBS is on the Vaccine Injury Table, Petitioner does not assert a Table GBS claim; nor would such a claim be viable.

appears to be based on a hospitalization from June 2017. *Id.* at ¶ 15. The case was assigned to the Special Processing Unit of the Office of Special Masters.

For the reasons discussed below, I find that the petition was not filed within the time permitted by section 16(a)(2) of the Vaccine Act. In addition, Petitioner has not established by preponderant evidence that he suffered from GBS caused in fact by his flu vaccination. Therefore, the case is dismissed.

# I. Relevant Procedural History

On September 23, 2022, Respondent filed his Rule 4(c) Report and motion to dismiss (ECF No. 31). Following a status conference, Petitioner was given additional time to determine how he wished to proceed (ECF No. 32). On February 12, 2023, Petitioner filed a status report requesting "an extended amount of time to rule on Respondent's Rule 4(c) Report and Motion to Dismiss. Petitioner wishes to seek additional opinions from potential counsel" (ECF No. 33). On June 20, 2023, Petitioner filed a status report stating that "Petitioner's counsel had no further information from the previous status report filed on February 12, 2023. Petitioner indicated that he would like more time to obtain additional counsel, however no communication has been made to Petitioner's counsel on Petitioner's behalf" (ECF No. 34).

On September 18, 2023, I issued an order concerning the deficiencies identified in motion to dismiss, and allowing Petitioner an opportunity to respond to the motion or dismiss the claim by November 20, 2023 (ECF No. 35). On November 20, 2023, Petitioner filed a status report stating that counsel "has no further information from the previous status report filed on June 20, 2023." (ECF No. 36). Petitioner's counsel stated that in January of 2023, Petitioner indicated that he wanted more time to obtain additional counsel, but "no further communication has been made to Petitioner's counsel on Petitioner's behalf." *Id.* Counsel added that she "does not have authorization from Petitioner to file a motion, notice, or stipulation to dismiss on Petitioner's behalf." *Id.* No further documentation has been filed. Despite numerous opportunities, Petitioner has not responded to the motion to dismiss. The issue of whether the petition should be dismissed is now ripe for resolution.

### II. Legal Standards

The Vaccine Act statute of limitations provides that no petition for an alleged vaccine-related injury may be filed "after the expiration of 36 months after the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of such injury." Section 16(a)(2). The statute begins to run from the manifestation of the first objectively recognizable symptom, regardless of whether that symptom is sufficient for diagnosis. *Id.*; *Carson v. Sec'y of Health & Human Servs.*, 727 F.3d 1365, 1369 (Fed. Cir. 2013); *Barger v. Sec'y of Health & Human Servs.*, No. 23-939V, 2024 WL 1181272 (Fed. Cl. Spec. Mstr. Feb. 20, 2024).

Under Section 13(a)(1)(A) of the Act, a petitioner must demonstrate, by a preponderance of the evidence, that all requirements for a petition set forth in section 11(c)(1) have been satisfied. A petitioner may prevail on his claim if he has "sustained, or endured the significant aggravation of any illness, disability, injury, or condition" set forth in the Vaccine Injury Table (the Table). Section 11(c)(1)(C)(i). The most recent version of the Table, which can be found at 42 C.F.R. § 100.3, identifies the vaccines covered under the Program, the corresponding injuries, and the time period in which the particular injuries must occur after vaccination. Section 14(a). If petitioner establishes that the vaccinee has suffered a "Table Injury," causation is presumed.

If, however, the vaccinee suffered an injury that either is not listed in the Table or did not occur within the prescribed time frame, the petitioner must prove that the administered vaccine caused injury to receive Program compensation. Section 11(c)(1)(C)(ii) and (iii). In such circumstances, the petitioner asserts a "non-Table or [an] off-Table" claim and to prevail, must prove his claim by preponderant evidence. Section 13(a)(1)(A). This standard is "one of . . . simple preponderance, or 'more probable than not' causation." *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1279-80 (Fed. Cir. 2005) (referencing *Hellebrand v. Sec'y of Health & Human Servs.*, 999 F.2d 1565, 1572-73 (Fed. Cir. 1993)). The Federal Circuit has held that to establish an off-Table injury, petitioners must "prove . . . that the vaccine was not only a but-for cause of the injury but also a substantial factor in bringing about the injury." *Shyface v. Sec'y of Health & Human Servs.*, 165 F.3d 1344, 1351 (Fed. Cir 1999). *Id.* at 1352. The received vaccine, however, need not be the predominant cause of the injury. *Id.* at 1351.

The Federal Circuit has indicated that a petitioner "must show 'a medical theory causally connecting the vaccination and the injury" to establish that the vaccine was a substantial factor in bringing about the injury. *Shyface*, 165 F.3d at 1352-53 (quoting *Grant v. Sec'y of Health & Human Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992)). The Circuit Court added that "[t]here must be a 'logical sequence of cause and effect showing that the vaccination was the reason for the injury." *Id.* The Federal Circuit subsequently reiterated these requirements in its *Althen* decision. *See* 418 F.3d at 1278. *Althen* requires a petitioner

to show by preponderant evidence that the vaccination brought about her injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.

Id. All three prongs of Althen must be satisfied. Id.

Finding that a petitioner is entitled to compensation must not be "based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion." Section 13(a)(1). Further, contemporaneous medical records are presumed to be accurate and complete in their recording of all relevant information as to petitioner's medical issues. *Cucuras v. Sec'y of Health & Human Servs.*, 993, F.2d 1525, 1528 (Fed. Cir. 1993). Testimony offered after the events in questions is considered less reliable than contemporaneous reports because the need for accurate explanation of symptoms is more immediate. *Reusser v. Sec'y of Health & Human Servs.*, 28 Fed. Cl. 516, 523 (1993).

An off-Table significant aggravation claim is brought by filing a petition asserting that a petitioner:

- (ii)(I) sustained, or had significantly aggravated, any illness, disability, injury, or condition not set forth in the Vaccine Injury Table but which was caused by a vaccine referred to in subparagraph (A), or
- (II) sustained, or had significantly aggravated, any illness, disability, injury, or condition set forth in the Vaccine Injury Table the first symptom or manifestation of the onset or significant aggravation of which did not

occur within the time period set forth in the Table but which was caused by a vaccine referred to in subparagraph (A)

Vaccine Act § 11(c)(1)(C)(ii).

A prima facie case of significant aggravation of an off-Table injury requires proof, by a preponderance of the evidence, of six elements: (1) the person's condition prior to vaccine administration; (2) the person's current condition; (3) whether the person's current condition constitutes a 'significant aggravation'; (4) a medical theory causally connecting such a worsened condition to the vaccine; (5) a logical sequence of cause and effect showing that the vaccination was the reason for the significant aggravation; and (6) a showing of a proximate temporal relationship between the vaccination and significant aggravation. *Loving v. Sec'y of Health & Human Servs.*, 86 Fed. Cl. 135, 144 (2009). The Vaccine Act defines significant aggravation as "any change for the worse in a preexisting condition which results in markedly greater disability, pain, or illness accompanied by substantial deterioration of health." Section 33(4).

In *Sharpe v. Sec'y of Health & Hum. Servs.*, 964 F.3d 1072 (Fed. Cir. 2020), the Federal Circuit further elaborated on the *Loving* framework. Under Prong (3) of the *Loving* test, a petitioner need not demonstrate an *expected* outcome, but merely that his current-post vaccination condition was worse than pre-vaccination. *Sharpe*, 964 F.3d at 1081. A claimant may establish a prima facie case of significant aggravation without eliminating another potential alternate cause. *Id.* at 1083.

## III. Relevant Factual History

#### A. Medical Records

On November 23, 2016, Petitioner received a flu vaccine. Ex. 1 at 4. Five and a half months later, on May 12, 2017, he went to a Department of Veterans Affairs ("VA") emergency department ("ED"), reporting "cough/cold/congestion with yellow phlegm x 2 weeks." Ex. 9 (ECF No. 23-1) at 345-46. He was diagnosed with an upper respiratory infection and discharged with medications. *Id.* at 347-49.

Two days later (May 14, 2017), Petitioner returned to the VA ED reporting headaches in addition to chest and back pains. Ex. 9 at 342. He was discharged in stable condition and instructed to rest, take fluids, continue current medications, alternate Motrin and Tylenol, use Tramadol for severe pain, follow up with his primary care physician ("PCP"), and return for worsening or changes. *Id.* at 344.

The next day, on May 15, 2017, Petitioner returned to the VA ED. Ex. 9 at 336. He reported worsening of all of his prior symptoms, and in addition his mouth was numb, his lower abdomen was painful, and he had vomited a couple of times. *Id.* He was admitted for observation. *Id.* at 341. He remained hospitalized until sometime between May 16-18.<sup>4</sup> *Id.* at 25. He was diagnosed with complex migraine, thoracolumbar muscle spasms, dyspepsia, PTSD, and dysphagia. *Id.* 

Petitioner spoke with his PCP by phone on May 19, 2017, reporting that he was still having some facial numbness, difficulty opening his mouth, and headaches. Ex. 7 (ECF No. 13-8) at 112.<sup>5</sup> He was having some blurry vision, but denied other neurological symptoms. *Id.* 

A week later, on May 26, 2017, Petitioner saw his PCP Dr. Theo Mwamba to follow up on his hospital discharge. Ex. 9 at 306. He had lost about 15 pounds in two weeks due to jaw pain and difficulty chewing. *Id.* at 307. He was having issues with balance as well. *Id.* Dr. Mwamba noted that Petitioner's presentation was complex. *Id.* He ordered scans and tests, and referred Petitioner for evaluation to rule out a mental illness such as conversion disorder. *Id.* 

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<sup>&</sup>lt;sup>4</sup> The discharge summary has three different discharge dates. Ex. 9. The header of the discharge summary has a discharge date of May 16, 2017. Ex. 9 at 25. Just below that, it notes a discharge date of 5/17/17. *Id.* Within the text of the summary, it states "[h]e was sent home in stable condition on 5/18/17." *Id.* at 26. For purposes of this Decision, the precise discharge date is not relevant.

<sup>&</sup>lt;sup>5</sup> Petitioner filed Exhibit 7 in two parts that are not properly labeled or paginated. Thus, I refer to the two parts using the ECF document numbers (ECF Nos. 13-7 and 13-8) and the page numbers added to the PDFs by CM/ECF.

Petitioner returned to the ED on June 1, 2017, complaining of a headache, neck pain, facial numbness, and difficulty eating. Ex. 9 at 303. He was discharged with diagnoses of degenerative joint disease and spinal stenosis. Id. at 305.

Twelve days later, on June 13, 2017, Petitioner saw neurologist Dr. Nasir Waheed. Ex. 9 at 297. He reported intermittent daily headaches and weakness in his face and lower extremities. Id. at 297-298. Dr. Waheed noted that Petitioner "seems to have developed some new symptoms and signs since last seen in the hospital, which would need further work up." *Id.* at 298. Petitioner elected to go to the ED. *Id.* 

That day (June 13, 2017), Petitioner went to the ED and was admitted to the hospital. Ex. 9 at 280. He had first noticed upper respiratory symptoms about six weeks earlier, and developed headaches with occasional blurred vision and diplopia. Id. Within days he developed facial palsy and was thought to have a complex migraine. Id. On examination, it appeared as though he did have "true palsies." Id. Petitioner reported that his symptoms of neck pain, headache, bilateral facial weakness, and generalized weakness had not worsened or improved since they initially began almost a month earlier. Id. at 282. He was unable to smile, frown, or lift his brows, and had bilateral facial weakness. Id. at 283. The differential diagnoses included Lyme disease, bilateral Bell's palsy, syphilis, Myasthenia Gravis, GBS, and Lambert-Eaton. *Id.* at 285.

While hospitalized, a lumbar puncture revealed elevated cerebrospinal fluid protein levels, suggesting GBS, likely variant Miller Fisher Syndrome. Ex. 9 at 21. His treating doctors considered that his GBS may have been triggered by his prior upper respiratory infection, noting that "patient's symptoms all precipitated following an upper viral illness." Id. He underwent a five day course of IVIG, without much objective improvement. Id. at 22. He was discharged on June 20, 2017 and instructed to follow up with neurology and to continue physical and occupational therapies on an outpatient basis. Id. at 21-22. Petitioner thereafter continued care on an outpatient basis. See generally Ex. 9.

#### B. Affidavit Evidence

Petitioner filed an affidavit in support of his claim. Ex. 5<sup>6</sup> (ECF No. 13-5). Petitioner asserts that he suffered from GBS that was formally diagnosed on or around June 19, 2017, during his second hospitalization - and after his previous symptoms were significantly aggravated. Ex. 5 at ¶ 1. He maintains symptoms began in March 2017,7

<sup>6</sup> Petitioner filed two affidavits designated as Exhibit 5, ECF Nos. 1-7 and 13-5. The only difference appears to be the addition of a paragraph affirming that he had not filed a prior civil action in the second one. For purposes of this order, I refer to the second affidavit, ECF No. 13-5, as Exhibit 5.

<sup>&</sup>lt;sup>7</sup> Although Petitioner states his symptoms began and he went to the ED in *March* 2017, it appears that he is referring to his May ED visits. Having reviewed the VA records, the only record from March 2017 is a March 14, 2017 letter from the VA to Petitioner stating that they had been trying to reach him to schedule a clinic appointment. Ex. 9 (ECF 23-1) at 348-49. Additionally, his treatment records in mid-June 2017 refer to symptoms beginning approximately one month earlier. Id. at 20, 281.

starting with a "bad chest cold." Id. at ¶ 10. He went to the ED and was discharged the same day. Id.

Petitioner returned to the ED on May 14, 2017, with worsening symptoms. Ex. 5 at  $\P$  11. Doctors were unable to determine the cause of his symptoms, and he was sent home. *Id.* at  $\P\P$  12-13. Thereafter, he states he lost 26 pounds and his "pain significantly increased . . . and my injury significantly aggravated." *Id.* at  $\P\P$  15-16.

He states that "due to the significant aggravation of [his] symptoms, including [his] weight loss," he was readmitted to the hospital from June 13-20, 2017. Ex. 5 at  $\P$  17. During that hospitalization, based on results of a spinal tap, he was diagnosed with GBS and treated with IVIG. *Id.* at  $\P\P$  18-19.

Following discharge, he continued IVIG treatments. Ex. 5 at ¶ 21. His mobility returned, and he began walking with a cane. *Id.* at ¶¶ 22-23. Some other symptoms, such as cheek and facial paralysis, have not gone away. *Id.* at ¶ 22.

# IV. Parties' Arguments

Respondent argues that that this case is not appropriate for compensation and should be dismissed for several reasons. Respondent's Rule 4(c) Report and Motion to Dismiss, filed Sept. 23, 2022 (ECF No. 31) ("Motion to Dismiss"). First, Respondent argues that Petitioner had not offered a reputable medical or scientific theory in support of vaccine-related GBS. Motion to Dismiss at \*9. Moreover, Respondent asserts that the contemporaneous medical records "do not support the onset of petitioner's alleged GBS within a timeframe in which vaccine causation could be ascribed." *Id.* Respondent adds that asserting GBS caused by a flu vaccine with onset five to six months after vaccination may lack a reasonable basis. *Id.* 

Respondent further asserts that there is evidence of an alternative cause for Petitioner's alleged GBS, noting that he was diagnosed with an upper respiratory infection in May of 2017. Motion to Dismiss at \*9. Respondent adds that Petitioner's claim was filed more than 36 months after the onset of his condition and thus is time-barred. *Id.* Respondent states that Petitioner's medical records document that he began experiencing symptoms of a GBS variant on May 14, 2017, but did not file the petition until June 17, 2020, approximately one month after the limitations period expired. *Id.* at \*10.

Respondent states that the petition appears to take the position that the statute of limitations began to run during his June 13 to June 20, 2017 hospitalization, when his condition was 'significantly aggravated.' Motion to Dismiss at \*10-11. However, Respondent distinguishes between a worsening of Petitioner's condition and a significant aggravation claim, and asserts that Petitioner has not satisfied the six-part test for a significant aggravation claim set forth in *Loving*, 86 Fed. Cl. 135. *Id.* Respondent explains that there is "absolutely no evidence to suggest that petitioner had GBS before receiving

the flu vaccine on November 23, 2016, so there is no basis for making a significant aggravation claim." *Id*.

Petitioner has not responded to the motion to dismiss.

# V. Analysis

## A. Statute of Limitations

To be timely, a petition must be filed within 36 months of the first symptom or manifestation of onset, or the significant aggravation, of an injury. Section 16(a)(2). In this case, for the petition to be timely, Petitioner must show that the first symptom or manifestation of onset, or the significant aggravation of a preexisting injury, occurred less than 36 months before the petition was filed, i.e., no earlier than June 17, 2017. But the record preponderates against such a determination.

Rather, the record clearly demonstrates that Petitioner's neurological symptoms began by *no later than* some time in mid-May 2017. When Petitioner reported to the ED on May 15, 2017, he reported mouth numbness. Ex. 9 at 338; see also Ex. 7 (ECF No. 13-8) at 112 (complaining of facial numbness on May 19, 2017). Petitioner was subsequently admitted to the hospital for the symptoms that led to his GBS diagnosis on June 13, 2017. Ex. 9 at 299. These symptoms included weakness in his face and lower extremities, generalized weakness, facial palsy, blurred vision, and headaches. Ex. 9 at 282-84.

Give the above, no straightforward causation-in-fact claim could be based on such an onset and be timely, since this matter was filed more than three years later, in June 2020 rather than May. The same conclusion holds for even a significant aggravation claim – for even if Petitioner's June 2017 symptoms reflected some "aggravation," they occurred so long after the November 2016 vaccination that they could not credibly be linked to it, meaning no intervening vaccination occurred at all. The Petition was thus untimely.

## **B.** Onset

The Petition's deficiencies go well beyond the case's untimeliness. In particular, the onset of Petitioner's symptoms fell far outside of a facially-plausible timeframe.

The onset of Petitioner's GBS symptoms occurred, at the earliest, in May of 2017, which is *over five months* after vaccination. This is months outside of the Table timeframe of 3-42 days for a GBS claim. It is also far beyond the longest medically-acceptable timeframe that has been recognized in Vaccine Program cases, generally six to eight

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<sup>&</sup>lt;sup>8</sup> In fact, *even* if Petitioner could point to a vaccination that occurred after an alleged May 2017 onset, the record supports the conclusion that his purported aggravation began on June 13, 2017 – meaning any petition based on it would have to have been initiated by no later than June 15, 2020 (since June 13<sup>th</sup> was a Saturday that year) – not two days after.

weeks. See Chinea v. Sec'y of Health & Human Servs., No. 15-095V, 2019 WL 1873322, at \*29 (Fed. Cl. Spec. Mstr. Mar. 15, 2019) ("[i]n most successful non-Table cases, onset of symptoms is demonstrated to have occurred no longer than six to eight weeks after vaccination . . . . I am aware of no published Vaccine Program decisions that have found a timeframe longer than two months to be medically acceptable"); see also Benenhaley v. Sec'y of Health & Human Servs., No. 20-0545V, 2022 WL 17974426, at \*5 (Fed. Cl. Spec. Mstr. Nov. 28 2022) (dismissing case alleging GBS with onset 109 days after vaccination); James v. Sec'y of Health & Human Servs., No. 19-1357V, 2021 WL 1413814 (Fed. Cl. Spec. Mstr. Mar. 15, 2021) (finding onset of GBS was four months after vaccination, too late for a Table or off Table claim, and thus dismissing); Ray v. Sec'y of Health & Human Servs., No. 20-321V, 2021 WL 778435 (Fed. Cl. Spec. Mstr. Jan. 13, 2021) (dismissing Table GBS claim based on finding that onset of symptoms occurred over 70 days after vaccination); Finch v. Sec'y of Health & Human Servs., No. 17-675V, 2018 WL 818265 (Fed. Cl. Spec. Mstr. Jan. 19, 2018) (noting that if Petitioner had GBS, the onset thereof was five months after vaccination, and dismissing claim).

While the records do seem to suggest that Petitioner suffered from GBS, his symptoms began far too long post-vaccination to be credibly associated with that prior event.<sup>9</sup>

#### Conclusion

Respondent's motion to dismiss is GRANTED and this case is DISMISSED as untimely and for insufficient evidence. The Clerk of Court shall enter judgment accordingly.<sup>10</sup>

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<sup>&</sup>lt;sup>9</sup> In addition, Petitioner's treating physicians considered his upper respiratory infection as a potential cause of his GBS. See, e.g., Chinea, 2019 WL 1873322, at \*28 ("two-thirds of GBS cases follow an antecedent infection (typically an upper respiratory or gastrointestinal infection) beginning a few weeks prior to symptoms onset"); Rupert v. Sec'y of Health & Human Servs., No. 10-160V, 2014 WL 785256 (Fed. Cl. Spec. Mstr. Feb. 3, 2014) (dismissing GBS claim because preponderant evidence established that Petitioner's GBS was caused not by vaccine but by a factor unrelated to vaccination, an antecedent upper respiratory infection).

<sup>&</sup>lt;sup>10</sup> Pursuant to Vaccine Rule 11(a), entry of judgment can be expedited by the parties' joint filing of notice renouncing the right to seek review.

IT IS SO ORDERED.

s/Brian H. Corcoran
Brian H. Corcoran
Chief Special Master